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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,712	WAKAMIYA, NOBUTAKA	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *156-219* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *156-219* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/9/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Paper filed 9 August 2004 in response to the Non-Final Office Action mailed 10 March 2004. Claims 97-155 were considered in the 10 March Office Action. Claims 97-155 were canceled and claims 156-219 were added in the 9 August Paper. Claims 156-219 are pending and under consideration.

Response to Amendment

Rejection of claims 97-155 is rendered moot by cancellation of the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. §112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001

The Examiner is using the following definitions in evaluating the claims for utility.

"Specific"-A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial"-A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible"- Credibility is assessed for the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established"-a specific, substantial and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material alone or taken with the knowledge of one skilled in the art.

Claims 156-219 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The reasons for this rejection are the same as those set forth in the 29 April 2003 and 10 March 2004 Office Actions with regard to the previously pending claims. To summarize:

As stated in the 29 April Office Action, on page 47 the specification sets forth the industrial applicability of the claimed invention as, "useful for investigating mechanisms of biological defense systems, and may provide medical, experimental tools in which biological activities of the novel collectin are utilized. For example, vectors that can express the novel collectin, host cells comprising the vector with feasibility of expression, antibodies for the novel collectin, as well as probes for screening the related molecular species of the novel collectin can be provided. In addition, transgenic non-human animals...are provided, which may be utilized as disease model animals for studies on functions, or regulation of expression of the novel collectin". The specification provides no teachings regarding the unique function of the novel collectin (i.e., those functions arising from its novel structure) and only vague statements regarding its role in host defense. As the specification provides no specific function for the protein and does not identify a single specific condition that could be diagnosed or treated according to the teachings of the specification, it fails to provide a specific utility for the claimed polypeptide, nucleic acid and transgenic animal.

Furthermore, the asserted industrial applicability of the claimed Inventions is mostly directed to identifying the biological activity of the novel collectin and then utilizing the claimed

products to diagnose or treat diseases based on that biological activity, whatever it might be. This amounts to an invitation to the skilled artisan to experiment in order to discover the utility of the claimed invention. Therefore the utility provided in the specification is not substantial.

With regard to well-established utility, the specification generally teaches that the novel collectin might be involved in innate immunity based on homology to a family of proteins having Ca^{2+}-dependent carbohydrate recognition regions and collagen-like regions known as collectins. The disclosure teaches only a fragment of the naturally occurring polypeptide, which does not comprise the membrane-spanning domain, and asserts that the disclosed polypeptide is functionally related to a family of soluble proteins. Although it is possible that the extracellular fragment of the naturally occurring novel collectin might have activity similar to a known collectin, the skilled artisan would not be able to identify a well-established utility for the soluble portion of the novel collectin described in the application. Of the known collectins, the sequence set forth as SEQ ID NO:2 is most homologous to SP-D, a collectin found in pulmonary surfactant capable of binding microorganisms and stimulating chemotaxis of phagocytes and production of oxygen radicals (see Hansen *et al.* (1998) *Immunobiol.* 199:165-189, especially the second full paragraph on page 166). However, SEQ ID NO:2 shares only 35% identity with SP-D over 304 amino acids. The Office Action cites several teachings demonstrating that the art generally acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases such that a specific and substantial utility is readily apparent. The Office Action asserts, given that the structural homology of the instant SEQ ID NO:2 to known collectins is 35%, at best, the function of the extracellular portion of the novel collectin described in the specification would be expected to be related to the function of other

collectin family members in broad, general terms which do not suffice to assign a well-established utility to the claimed polypeptide.

In the 9 August Paper, Applicant asserts, "[t]he Office has alleged that the claimed subject matter lacks utility because the amino acid sequence of the claimed polypeptide constitutes a portion of a larger polypeptide" and, "[t]he Office Alleged that the asserted utility of the claimed subject matter is somehow incorrect in view of the utility of the scavenger receptor" (page 11).

It should be made clear that Applicant's assertions are based on statements made in the 10 March Office Action in reply to Applicant's own statement that collectins are structurally and functionally different from scavenger receptor proteins (see page 4, first full paragraph of the 10 March Office Action). Thus, it was Applicant that first asserted that identification of the claimed invention as a portion of a scavenger receptor suggests that it would not function as a collectin. The comments made by the Examiner were predicated on Applicant's own assertion that the "true nature" of the claimed invention was in conflict with the utility as a collectin.

As described above, the *prima facie* case for lack of a specific and substantial utility is based on the failure of the specification to disclose the unique properties of the "novel collectin" such that the skilled artisan would know the specific utility of the claimed invention. For example, on page 47, the specification teaches that the invention is "useful for investigating mechanisms of biological defense systems", but this utility is common to any protein having some possible role in host defense. Applicant is reminded that an asserted utility as a tool to understand the functional properties of the claimed invention is not substantial. Therefore, investigating mechanisms of biological defense systems is not a substantial utility for the

claimed invention unless the known properties of the invention can be used to reveal new properties of other aspects of the biological defense system. This is in contrast to using known properties of the biological defense system to reveal the functional properties of the claimed invention. As the specific functional properties of the claimed invention have not been disclosed in the present application, the invention is not useful to investigate anything other than the properties of the invention itself, which is not a substantial utility. Likewise, the specification teaches that the invention "may provide medical, experimental tools in which biological activities of the novel collectin are utilized", but any protein may provide medical, experimental tools in which biological activities of the protein are utilized. This is not a specific and substantial utility unless the biological activities of the novel protein are also disclosed in specific terms such that the skilled artisan would know specifically the "real world" use to which the medical, experimental tools can be applied.

Applicant urges that utility does not require perfection and cites passages from the MPEP, which state "'[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result'" and "'courts have been reluctant to uphold a rejection under 35 U.S.C. §101 solely on the basis that the Applicant's opinion as to the nature of the specific and substantial utility was inaccurate.'" (page 12).

These statements are not deemed persuasive because, when viewed in context, they do not support Applicant's contention that the utilities asserted in the instant disclosure meet the requirements of 35 U.S.C. §101. The former statement is clearly referring to the requirements for credible utility, it has not been asserted that the utilities set forth in the specification are incredible and therefore the statement is not relevant to the present rejection. The former

statement reads, as a whole, "[w]here an applicant has set forth a specific and substantial utility, courts have been reluctant to uphold a rejection under 35 U.S.C. 101 solely on the basis that the applicant's opinion as to the nature of the specific and substantial utility was inaccurate." The claims are rejected on the grounds that the utilities asserted in the application are neither specific nor substantial, not on the grounds that there is an inaccurate asserted specific and substantial utility. Thus, the rejection is not based "solely on the basis that applicant's opinion as to the nature of the specific and substantial utility was inaccurate."

With regard to well-established utility, Applicant urges that the identification of the invention as a collectin is sufficient to establish utility under 35 U.S.C. §101. Applicant cites statements from the specification teaching that collectins have established properties, "*e.g.*, antibacterial and anti-viral activity" and the alignment of the claimed polypeptide with sequences of known collectins. Applicant cites MPEP §2107.03, which states, "Courts have routinely found evidence of structural similarity to a compound known to have particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound."

These arguments have been fully considered but are not deemed persuasive. No specific and substantial utility is well known, immediately apparent, or implied by the specification's disclosure of the properties of the polypeptide of the claims alone or taken with the knowledge of one skilled in the art. The property of the claimed material disclosed in the specification is limited sequence homology with a portion of three known collectin molecules. Figure 5 shows that an alignment of a 210 amino acid fragment of the instant protein with an 85 amino acid fragment of the 248 amino acid MBP, an 87 amino acid fragment of the 248 amino acid SP-A

protein and a 207 amino acid fragment of the SP-D protein. The homology to the MBP and SP-A proteins is extremely low, even over these limited regions, and, as pointed out in previous Office Actions, the homology with SP-D is only 35%. Given that the art recognizes a high degree of unpredictability in the assessing the functional characteristics of a protein based on such a low degree of similarity (discussed in detail in the 29 April Office Action, page 7), the functional properties, and hence the utility of claimed invention would not be readily apparent to the skilled artisan.

The Courts position with regard to a compound having structural similarity to a compound known to have particular therapeutic of pharmacological utility is not germane to the instant case because the polypeptide of the instant claims does not have a degree of structural similarity to MBP, SP-A and SP-D that would indicate that the proteins have the same therapeutic activity, and, furthermore, there is nothing on the record that would indicate that any of the collectin proteins have an established therapeutic activity. A review of the collectin art published two years after the effective filing date of the instant application (Holmskov (2000) *APMIS* 108: 1-59) makes no mention of established clinical utility for any collectin molecule and the Examiner can find no evidence that even clinical trials of collectins were underway at the time of filing.

Applicant alleges that several publications of record support the designation of the claimed subject matter as a collectin and particularly points out that Hoppe and Reid describe the common structure of collectins, which is consistent with the collectin claimed in the application and described in the specification. However, the Examiner can find no discussion of where the domains identified by Hoppe and Reid as characteristic of collectin proteins (See, *e.g.*, Fig. 1 and

the caption thereto) can be found in the claimed polypeptide. Instead, it would seem that the claimed polypeptide has been identified as a collectin based on similarity to a 27 amino acid fragment of MBP (Example 1). As pointed out by Applicant in the Paper filed 11 November 2003, "scavenger receptor proteins cannot take on an oligomeric form", which Hoppe and Reid show is characteristic of all collectins. Thus, the polypeptide of the present claims, being a scavenger receptor, would not be expected to form the higher order structure characteristic of collectins. Given this substantial departure from canonical collectin structure, and the low degree of overall similarity of the claimed invention to any protein belonging to the collectin family, one of ordinary skill would expect that there are specific functional characteristics of the invention, critical to its function and utility, which are not disclosed in the application. Therefore, the utility of the claimed invention would not be readily apparent to one of ordinary skill in the art at the time of filing.

In the concluding paragraph, Applicant asserts that the claimed invention comprises a specific utility because the protein binds to saccharides in a calcium dependent manner and not all proteins have this property. However, applicant is reminded that a specific utility is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Proteins capable of binding saccharides, or even proteins belonging to the collectin family are a broad class of invention, and a utility based on the general properties of saccharide-binding proteins or collectin family members is not a specific utility.

Applicant urges that the specification asserts a substantial utility in teaching that the claimed invention has utility as an anti-viral compound in the inhibition of infection. However, Applicant is reminded that utilities that require carrying out further research to identify or

reasonably confirm a "real world" context of use are not substantial utilities. Given the low structural homology of the instant protein with any compound known to have antiviral activity, and the absence of any established use of collectins as anti-viral agents at the time of filing, reasonably confirming that the claimed invention could be used as an anti-viral agent would require significant further research.

Declaration under 37 CFR 1.132

Applicant asserts that the showings of the declaration under 37 CFR 1.132 filed with the 9 August paper confirm that the claimed invention has utility as set forth in the specification. The declaration demonstrates that a 159 amino acid fragment of the polypeptide set forth as SEQ ID NO: 2 is capable of binding various labeled saccharides in a Ca^{2+} dependent fashion.

These showings are insufficient to overcome the present rejection because they do not confirm a specific and substantial utility, which has basis in the specification. For reasons provided in the previous Office Action and herein above, the specification fails to disclose a specific and substantial asserted utility for the claimed invention and fails to disclose the properties of the invention such that a well-established utility would be readily apparent to the skilled artisan. Demonstrating that a fragment of the polypeptide comprised within the protein of the claims binds saccharides does not cure this deficiency because there is no asserted or well-established utility for a polypeptide that merely binds polysaccharides. The declaration establishes that a portion of the polypeptide of the claims has one characteristic in common with collectins, as well as other lectins. It is noted, however, that the art recognizes many critical functional characteristics of collectins beyond merely binding to saccharides (see Holmskov

(*supra*) Chapter 5, pages 28-35). Based on the data provided Applicant asserts that "the claimed polypeptide comprises a collectin and possesses utility(ies) associated with the same". Applicant is urged to explicitly state what utilities, disclosed in the specification or readily apparent to the skilled artisan, are supported by the demonstration that a fragment of the protein of the claims binds saccharides.

Applicant's arguments and the evidence provided in the declaration under 37 CFR 1.132 have been fully considered. However, the based on a careful consideration of the record as a whole, the arguments and evidence are not deemed persuasive. Therefore, claims 156-219 are rejected under 35 U.S.C. §101 as lacking a specific and substantial asserted utility or a well-established utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 156-219 are rejected under 35 U.S.C. 112, first paragraph, as lacking an enabling disclosure. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 158, 162, 164, 167, 169, 172, 174, 177, 179, 182, 184, 187, 189, 192, 194, 197 and 219 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The claims are directed to isolated polypeptides and polynucleotides, wherein the claimed polypeptide encompasses any polypeptide encoded by a polynucleotide that hybridizes to a polynucleotide complementary to a fragment of the nucleic acid set forth as SEQ ID NO: 1 or wherein the polynucleotide comprises a nucleotide sequence that hybridizes to a polynucleotide complementary to a fragment of the nucleic acid sequence set forth as SEQ ID NO: 1. According to the hybridization conditions set forth in the claims, the nucleic acids need only have sufficient homology to hybridize under low stringency, or in the case of claim 219, no stringency parameters are specified. As stated in the 29 April Office Action, the claimed genera of nucleic acids and polypeptides encompass molecules having shared functional domains and only limited structural similarity. An adequate written description of a molecule requires more than a mere statement that it is part of the invention and reference to a potential method for

isolating it; what is required is a description of the molecule itself. It is not sufficient to define molecule solely by its principal biological property (i.e., it encodes or is a collectin) because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any molecule with that biological property. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, claiming all molecules that achieve a result without defining what means will do is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific molecules sequences, which provide the means for practicing the invention.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acids and polypeptides encompassed by the claims. Therefore, only the nucleic acids and proteins comprising or encoding the polypeptide and nucleic acid sequences explicitly set forth in the disclosure, or the fragments set forth in the claims wherein from 1 to 10 amino acids are deleted substituted or added meet the written description provision of 35 U.S.C. §112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Response to Arguments

Applicant's arguments are primarily directed to written description for nucleic acids and polypeptides comprising, as opposed to consisting of, the disclosed sequences and are found persuasive to the extent that the nucleic acids and proteins of the claims are limited to comprising the disclosed sequences.

With regard to variants of the disclosed nucleic acids, applicant cites Example 14 of the Written Description Guidelines as supporting the scope of the claims. Applicant urges that Example 14 specifically provides for claiming of polypeptide variants based on a single described amino acid sequence, in combination with the described amino acid sequence. This argument has been fully considered but is not deemed persuasive. Again, the facts in the instant case are significantly different from the facts in the cited Example.

The finding in Example 14 is based on the following reasoning: "[t]he specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity." In contrast, the instant claims encompass a genus of much broader scope than the genus of proteins having at least 95% structural identity to the disclosed sequence. For example, any polypeptide that binds a carbohydrate in a Ca^{2+} manner is

encompassed by claim 158 so long as the polypeptide can be encoded by polynucleotide that hybridizes to the fragment of SEQ ID NO: 1 under the low stringency conditions set forth in the claims. The Example makes clear that the limitation of the genus to comprising highly homologous structure is critical to the determination that the genus is adequately described by repeatedly reciting the structural limitation. Applicant's argument that Example 14 supports written description for the instant claims is not persuasive because Applicant is claiming a larger genus than what was considered in the Example. Applicant's arguments are not deemed persuasive; therefore, the claims are rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.
Examiner
Art Unit 1636